



Drug Enforcement Administration

Cypress Creek Pharmacy, LLC; Order

On October 18, 2019, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Cypress Creek Pharmacy, LLC (hereinafter, Applicant), of Wesley Chapel, Florida. Order to Show Cause (hereinafter, OSC), at 1. The OSC proposed the denial of Applicant's application for a DEA Certificate of Registration because, according to the OSC, Applicant's registration with DEA would be inconsistent with the public interest. *Id.* (citing 21 U.S.C. §§ 823(f) and 824(a)(4)).

In a Declaration dated August 3, 2021, a Diversion Investigator (hereinafter, the DI) assigned to the Tampa District Office, Miami Field Division, stated that on October 25, 2019, she met with Applicant's Registered Agent and Manager at the DEA Tampa District Office and "personally served him with a copy of the [OSC]." Request for Final Agency Action (hereinafter, RFAA), Exhibit (hereinafter, RFAAX) B, at 1-2. The DI also stated that since the service of the OSC, she has "received no communications from anyone acting on behalf of [Applicant] regarding the [OSC]." *Id.* at 2.

The Government filed a Request for Final Agency Action (hereinafter, RFAA) on September 3, 2021. In its RFAA, the Government stated that Applicant is without authority to handle controlled substances in Florida, because its state pharmacy license recently expired. RFAA, at 1. The Government provided documentation from the Florida Department of Health to support this claim. *See* RFAAX B-1 and B-2. The Government then requested that I deny Applicant's application for a DEA registration based solely¹ on the ground that Applicant lacks authority to handle controlled substances in Florida, the state where Applicant seeks a DEA

¹ The Government appears to have abandoned its public interest allegations in the RFAA, and therefore, I am not considering them.

registration. RFAA, at 1 and 6. The Government did not allege that Applicant lacked state authority in the OSC. *See generally* OSC.

Previous Agency decisions have stated that the Government is not required to issue an amended OSC to notice an allegation of a registrant's lack of state authority that arises during the pendency of a proceeding regarding a DEA registration. *Hatem M. Ataya, M.D.*, 81 Fed. Reg. 8221, 8244 (2016). Additionally, previous Agency decisions have stated that because the possession of state authority is a prerequisite for obtaining and maintaining a registration, the issue of state authority can be raised at any stage of a proceeding, even *sua sponte* by the Administrator. *See id.*; *see also Joe M. Morgan, D.O.*, 78 Fed. Reg. 61,961, 61,973-74 (2013). In those matters, however, the registrant had a meaningful opportunity, during at least one stage in the proceeding, to refute the Government's claim that the registrant lacked state authority. *See, e.g., Ataya*, 81 Fed. Reg. at 8245 (Administrator issued order directing parties to address whether registrant possessed state authority); *Lesly Pompy, M.D.*, 84 Fed. Reg. 57,749, 57,749-50 (2019) (notice provided during administrative hearing); *Morgan*, 78 Fed. Reg. at 61,973-74 (Government's post-hearing Motion for Summary Disposition provided adequate notice).

Here, the Government cited to *Lawrence E. Stewart, M.D.*, 86 Fed. Reg. 15,257 (2021), to support the proposition that it was not required to issue a new OSC demonstrating lack of state authority. RFAA, at 3-4. Although *Stewart* is accurately quoted, it also supports the notion that the Agency must give some sort of notice and an opportunity to contest the new allegations. In this case, in spite of changing the grounds for denial two years after issuance of the OSC, the Government had not demonstrated that it had given any such opportunity to the Applicant. Accordingly, on October 15, 2021, I issued an Interim Order to Applicant permitting it to submit a response addressing whether Applicant currently holds state authority to handle controlled substances in Florida within fifteen calendar days from the date that my office served the Order on Applicant. Applicant sent an email in reply to my Interim Order on October 20, 2021, stating, "I have closed the pharmacy and wish to close out of all matters dealing with the pharmacy and

the process of all licensure.”² Email dated October 20, 2021. I have received no further correspondence from Applicant regarding the Government’s allegations of its lack of state authority.

Because Applicant has presented no evidence or statements related to its lack of state authority, I consider the evidence submitted by the Government on the lack of state authority allegation to be uncontested.

I make the following findings of fact based on the record before me.

FINDINGS OF FACT

Applicant’s Application for a DEA Registration

On or about September 6, 2018, Applicant submitted an application for a DEA Certificate of Registration as a retail pharmacy in Schedules II through V with a proposed registered address at 26829 Tanic Drive, Suite 101, Wesley Chapel, Florida 33544. Applicant’s application was assigned Control No. W18097945A. RFAAX B, at 1.

The Status of Applicant’s State License

In her Declaration, the DI stated that Applicant’s state pharmacy license “expired, without renewal, on February 28, 2021.” RFAAX B, at 2. The Declaration noted that “that expiration was automatically extended until June 30, 2021 as part of the State of Florida’s COVID-19 response.” *Id.* at n.3.

According to Florida Department of Health’s online records, of which I take official notice, Applicant’s state pharmacy registration PH31651 is “delinquent”³ with a “license

² In spite of Applicant’s statement regarding its discontinuance of business, its application remains pending and I will continue to assess the application under 21 U.S.C. § 823. See *Lawrence E. Stewart, M.D.*, 86 Fed. Reg. 15,257 (2021).

³ According to the state website, “delinquent” means “[t]he license practitioner who held a CLEAR ACTIVE or CLEAR INACTIVE license, but failed to renew the license by the expiration date. The licensed practitioner is not authorized to practice in the [S]tate of Florida.” <https://mqa-internet.doh.state.fl.us/MQASearchServices/LicStatus.html#DELINQUENT>.

expiration date” of February 28, 2021.⁴ Florida Department of Health’s License Verification, Licensee Lookup, <https://mqa-internet.doh.state.fl.us/MQASearchServices/Home> (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of pharmacy in Florida, the state in which Applicant applied for registration with the DEA.

DISCUSSION

Pursuant to 21 U.S.C. § 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) “upon a finding that the registrant . . . has had [its] State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.” With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner’s registration. *See, e.g., James L. Hooper, M.D.*, 76 Fed. Reg. 71,371 (2011), *pet. for rev. denied*, 481 F. App’x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.*, 43 Fed. Reg. 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term “practitioner” to mean “a pharmacy . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.” 21 U.S.C. § 802(21). Second, in setting the requirements for obtaining a practitioner’s registration,

⁴ Under the Administrative Procedure Act, an agency “may take official notice of facts at any stage in a proceeding – even in the final decision.” United States Department of Justice, Attorney General’s Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. § 556(e), “[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.” Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by e-mail (dea.addo.attorneys@dea.usdoj.gov).

Congress directed that “[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. § 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner’s registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper*, 76 Fed. Reg. at 71,371-72; *Sheran Arden Yeates, M.D.*, 71 Fed. Reg. 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.*, 58 Fed. Reg. 51,104, 51,105 (1993); *Bobby Watts, M.D.*, 53 Fed. Reg. 11,919, 11,920 (1988); *Frederick Marsh Blanton*, 43 Fed. Reg. at 27,617.

According to Florida statute, “It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy: (a) which is not registered under the provisions of this chapter.”⁵ Fla. Stat. Ann. § 465.015(1). Further, “the practice of the profession of pharmacy” definition “includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug^[6]” Fla. Stat. Ann. § 465.003(13) (West, 2021).

Here, the undisputed evidence in the record is that Applicant currently lacks authority to operate a pharmacy in Florida. As already discussed, a pharmacy must be a licensed to dispense a medicinal drug, including a controlled substance, in Florida. Thus, because Applicant lacks authority to practice pharmacy in Florida and, therefore, is not authorized to dispense controlled substances in Florida, Applicant is not eligible to receive a DEA registration. Accordingly, I will order that Applicant’s application for a DEA registration be denied.

ORDER

⁵ The Government included an email from a Florida Medical Quality Assurance Investigator stating that “[p]harmacies are not allowed to operate at all on a delinquent license.” RFAA B-2, at 1 (emphasis in original). This statement is supported by my analysis of Florida law.

⁶ “Medicinal Drugs” or “Drugs” means “those substances or preparations commonly known as ‘prescription’ or ‘legend’ drugs which are required by federal or state law to be dispensed only on a prescription” Fla. Stat. Ann. § 465.003(8).

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I hereby order that the pending application for a Certificate of Registration, Control Number W18097945A, submitted by Cypress Creek Pharmacy, LLC is denied, as well as any other pending application of Cypress Creek Pharmacy, LLC for additional registration in Florida. This Order is effective [insert Date Thirty Days From the Date of Publication in the Federal Register].

Anne Milgram,
Administrator.

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